



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 179

[Docket No. FDA-1999-F-4617 (formerly Docket No. 1999F-5321)]

Irradiation in the Production, Processing and Handling of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of a 4.5 kilogray (kGy) maximum absorbed dose of ionizing radiation to treat unrefrigerated (as well as refrigerated) uncooked meat, meat byproducts, and certain meat food products to reduce levels of foodborne pathogens and extend shelf life. This action is in response to a petition filed by the U.S. Department of Agriculture, Food Safety and Inspection Service (USDA/FSIS).

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit either electronic or written objections and requests for a hearing by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. See section VIII of this document for information on the filing of objections.

ADDRESSES: You may submit either electronic or written objections and requests for a hearing identified by Docket No. FDA-1999-F-4617, by any of the following methods:

Electronic Submissions

Submit electronic objections in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written objections in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier (For paper or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-1999-F-4617 for this rulemaking. All objections received will be posted without change to <http://www.regulations.gov>, including any personal information provided. For detailed instructions on submitting objections, see the “Objections” heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or objections received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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I. Background

In a notice published in the Federal Register of December 22, 1999 (64 FR 71792), FDA announced that a food additive petition (FAP 9M4695) had been filed by the USDA/FSIS, 300 12th St. SW., rm. 112, Washington, DC 20250 (currently, Food Safety and Inspection Service, Stop Code 3782, Patriots Plaza III, Cubicle 8-163A, 1400 Independence Ave. SW., Washington, DC 20250-3700). The petition proposed that the food additive regulations in part 179, Irradiation

in the Production, Processing and Handling of Food (21 CFR part 179), be amended to provide for the safe use of a 4.5 kGy maximum dose of ionizing radiation to treat unrefrigerated (as well as refrigerated¹) uncooked meat, meat byproducts,² and certain meat food products to reduce levels of foodborne pathogens and extend shelf-life.

FDA's current regulation under § 179.26(b)(8) permits the irradiation of refrigerated or frozen, uncooked products that are meat within the meaning of 9 CFR 301.2(rr), meat byproducts within the meaning of 9 CFR 301.2(tt), or meat food products within the meaning of 9 CFR 301.2(uu), with or without nonfluid seasoning, that are otherwise composed solely of intact or ground meat, meat byproducts, or both meat and meat byproducts. The foods covered under § 179.26(b)(8) are subject to the Federal Meat Inspection Act (21 U.S.C. 601, et seq.), and, as described previously in this document, are defined by the USDA/FSIS in Title 9 of the Code of Federal Regulations. In this document, the term "meat" will be used to refer collectively to meat, meat byproducts, and certain meat food products applicable to this notice.

II. Safety Evaluation

FDA has previously reviewed the irradiation of meat and meat byproducts (62 FR 64107, December 3, 1997), and concluded that the irradiation of refrigerated meat and meat byproducts is safe. The current rulemaking concerns the irradiation of meat at temperatures that are above refrigerated temperature. FDA has previously reviewed and evaluated the safety of irradiated food products in a variety of applications. Discussions of these applications have been presented in various Federal Register documents (see, e.g., 62 FR 64107 and 70 FR 48057, August 16, 2005). FDA has also updated its review of the safety of irradiation of food with a thorough

¹ For the purpose of this final rule, refrigeration temperature is a maximum of 40°F (4°C).

² The Agency notes that in the filing notice dated December 22, 1999 (64 FR 71792), the phrase "meat products" was used while the petitioner used the phrase "meat byproducts" in their filing request dated August 19, 1999.

survey of the literature to the present time and found no new studies on the irradiation of meat (Ref. 1).

Under section 201(s) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(s)), a source of radiation used to treat food is a food additive. The additive is not added to food literally, but is rather a source of radiation used to process or treat food such that, analogous to other food processing technologies, its use can affect the characteristics of the food. Under section 409(c)(3)(A) of the FD&C Act (21 U.S.C. 348(c)(3)(A)), a food additive cannot be approved for a particular use unless a fair evaluation of the evidence establishes that the additive is safe under the conditions of that use. Importantly, the statute does not prescribe the safety tests to be performed but leaves that determination to the discretion and scientific expertise of FDA. Not all food additives require the same amount or type of testing to establish safety. The testing and data required to establish the safety of an additive will vary depending on the particular additive and its intended use.

In evaluating the safety of a source of radiation to treat food intended for human consumption, the Agency must identify the various effects that may result from irradiating the food and assess whether any of these effects pose a public health concern. In doing so, the following three general areas need to be addressed: (1) Potential toxicity, (2) nutritional adequacy, and (3) effects on the microbiological profile of the treated food. Each of these areas is discussed in this document.

The term “radiation chemistry” refers to the chemical reactions that occur as a result of the absorption of ionizing radiation. Because an understanding of radiation chemistry is fundamental in addressing these three areas, key aspects of radiation chemistry are also discussed.

FDA has fully considered the data and studies submitted in the subject petition as well as other data and information relevant to safety. The safety data that have been obtained from irradiating various foods under various conditions support conclusions about the safety of many irradiated foods, including unrefrigerated meat (Refs. 2 through 6).

A. Radiation Chemistry

The conditions under which foods are irradiated are important in considering the radiation chemistry of a given food. These conditions include: The radiation dose, the physical state of the food (e.g., frozen or dried), and the atmosphere in the package.

The radiolysis products generated in any food are directly proportional to the absorbed radiation dose (Ref. 2). Radiation-induced chemical changes may cause changes in the organoleptic properties of the food. The radiation chemistry of food is strongly influenced by the physical state of the food. If all other conditions, including radiation dose and ambient atmosphere, are the same, the extent of chemical change that occurs in a particular food in the frozen state is less than the change that occurs in the non-frozen state. This is because of the reduced mobility, in the frozen state, of the initial radiolysis products, which will tend to recombine rather than diffuse and react with other food components. For similar reasons, if all other conditions are the same, the extent of chemical change that occurs in the dehydrated state is less than the change that occurs in the fully hydrated state (62 FR 64107 at 64110 and references cited therein).

1. Radiation Chemistry of the Major Components of Meat

The major components of meat are proteins and lipids and the ratios vary. Ground beef is a food defined by USDA and ranges from 5 percent to 30 percent lipids. The ratio of protein to

lipid in whole cuts of beef varies depending on many factors.³ FDA has extensively reviewed the radiation chemistry of flesh foods⁴ in its rulemakings on the use of ionizing radiation to treat meat (62 FR 64107) and molluscan shellfish (70 FR 48057). In the meat rule (62 FR 64107 at 64111), FDA concluded: “In summary, the results obtained from chemical analyses of irradiated flesh foods establish that there would be very small amounts of individual radiolytic products generated by radiation doses comparable to those proposed in the petition. In addition, most of these radiolytic products are either the same as, or structurally very similar to, compounds found in foods that have not been irradiated. Because of their structural similarities to compounds found in foods that have not been irradiated, these radiolytic products would be expected to be toxicologically similar to such compounds as well. Thus, the available information regarding the radiation chemistry of the major components of flesh foods supports the proposition that there is no reason to suspect a toxicological hazard due to consumption of an irradiated flesh food.”

During its review of this food additive petition (FAP 9M4695), the Agency evaluated the changes that may occur from the irradiation of meat at temperatures greater than those previously approved. These evaluations are discussed in the following sections of this section II.A.1.

a. Proteins. As noted previously in this document, FDA has previously provided detailed discussions of the radiation chemistry of proteins in its rulemakings on the use of ionizing radiation to treat meat (62 FR 64107 at 64110) and molluscan shellfish (70 FR 48057 at 48059-48060). Those prior discussions support the findings in this rule. Studies conducted with high-protein foods (e.g., meat, poultry, and seafood), have established that most of the radiolysis products derived from food proteins have the same amino acid composition as the original protein and are altered only in their secondary and tertiary structures (i.e., they are denatured,

³ Information on the composition of foods can be found at: <http://www.nal.usda.gov/fnic/foodcomp/search/>; the USDA National Nutrient Database for Standard Reference. Search with keyword: meat.

⁴ Defined by USDA as meat, fish, poultry, and egg products.

Ref. 2). These changes are similar to those that occur as a result of heating, but in the case of irradiation, even at doses up to 50 kGy and when food is irradiated at temperatures ranging from -168°C to 60°C in various studies, such changes are far less pronounced than heating and the amounts of reaction products generated are far lower (62 FR 64107 at 64110). Based on these studies and on the analysis set forth in the prior rulemakings referenced previously in this document, FDA concludes that there will be no significant change in the amino acid composition of meat that is irradiated at doses up to 4.5 kGy at temperatures higher than refrigeration temperature.

b. Lipid. FDA has also previously provided detailed discussions of the radiation chemistry of lipids in the meat rule (62 FR 64107 at 64110-64111) and molluscan shellfish rule (70 FR 48057 at 48060). Those discussions also support this rule.

To summarize the previous discussions, a variety of radiolysis products derived from lipids have been identified. These include the following: Fatty acids, esters, aldehydes, ketones, alkanes, alkenes, and other hydrocarbons (Ref. 2). Identical or analogous products are found in foods that have not been irradiated. In particular, heating food produces generally the same types of products, but in amounts far greater than the trace amounts produced by irradiating food (62 FR 64107 at 64111 and references cited therein).

A class of radiolysis products that is derived from lipids, 2-alkylcyclobutanones (2-ACBs), has been reported to form in small quantities when fats are exposed to ionizing radiation. Any 2-ACB formed will depend on the fatty acid composition of the food, e.g., 2-dodecylcyclobutanone (2-DCB) is a radiation byproduct of palmitic acid (Refs. 7 and 8). In the molluscan shellfish rule, the Agency noted the reported creation of 2-DCB in irradiated chicken

and ground beef, which contain triglycerides with esterified palmitic acid. FDA did not find that the presence of low levels of 2-DCB raised a safety issue (70 FR 48057 at 48060).

2. Furan

During the course of reviewing the chemical effects of irradiation, FDA became aware of a report that suggested that the irradiation of apple juice might produce furan (Ref. 9). Because furan has been shown to cause tumors in laboratory animals, FDA has extensively researched the occurrence of furan in irradiated foods over the last 10 years. FDA has confirmed that certain foods form furan in low quantities when irradiated (Ref. 10). Studies conducted by FDA scientists and other researchers show that some foods form furan when heated and still other foods form furan during storage at refrigeration temperatures (Refs. 10 and 12). Testing of irradiated non-refrigerated meat found no furan at the limit of detection in the tests and detected no furan above the background levels of natural furan formation during storage (Refs. 10, 11, and 12). Therefore, the Agency concludes that the irradiation of meat at the requested maximum absorbed dose will not increase the amount of furan in the diet and does not present a toxicological hazard under the conditions proposed in the USDA/FSIS petition.

B. Toxicological Considerations

As discussed previously in this document, the available information from chemical analyses of irradiated foods suggests that there is no reason to suspect a toxicological hazard due to consumption of an irradiated food (Ref. 4.) The Agency notes that the large body of data from studies where irradiated foods were fed to laboratory animals provides an independent way to assess toxicological safety. These studies include those relied on by the Agency in previous evaluations of the safety of irradiated foods (see 51 FR 13376, April 18, 1986; 55 FR 18538, May 2, 1990; 62 FR 64107; 65 FR 45280, July 21, 2000; and 70 FR 48057, August 16, 2005).

The Agency is also relying on additional data and information in FDA files (Ref. 13). The Agency reviewed the data from chemical analysis of beef irradiated at 45 kGy (Ref. 19) and concluded that, although there will be an increase in the yields of some of the radiolysis products produced by irradiating meat at 30-40°C versus 5°C, the increase is no greater than an order of magnitude (Ref. 14), and is insignificant with respect to toxicity (Ref. 15).

In summary, FDA has reviewed data relevant to the assessment of potential toxicity of irradiated meat. While all of the studies are not of equal quality or rigor, the Agency has concluded that the quantity and breadth of testing and the number and significance of endpoints assessed would have identified any meaningful risk. Based on the totality of the evidence, FDA concludes that irradiation of meat under the conditions proposed in this petition does not present a toxicological hazard.

C. Nutritional Considerations

It has been established that the nutrient values of the macronutrients in the diet (protein, fats, and carbohydrates) are not significantly altered by irradiation at the petitioned doses (62 FR 64107 at 64114 and Refs. 16 and 17). Minerals (e.g., calcium and iron) are also unaffected by irradiation (62 FR 64107 at 64114 and Ref. 17). Levels of certain vitamins may be reduced as a result of irradiation. The extent to which this reduction occurs depends on the specific vitamin, the type of food, and the conditions of irradiation. Not all vitamin loss is nutritionally significant; the extent to which the reduction in a specific vitamin level is significant depends on the relative contribution of the food in question to the total dietary intake of the vitamin (62 FR 64107 at 64114).

FDA has extensively reviewed the nutritional losses that occur when meat is irradiated (62 FR 64107 at 64114). During this review, FDA noted that the majority of meat would be

irradiated at refrigerated temperatures or frozen, and possibly in a reduced oxygen environment, which would reduce the loss of vitamins. Although this rule covers irradiation of meat under unrefrigerated conditions, FDA concludes that this difference in temperature will not result in significant vitamin loss. Thiamine is known to be more sensitive to irradiation than other vitamins; FDA considered a worst-case scenario (e.g., thiamine levels in all these foods would be reduced by 50 percent) and the Agency concluded that, if all flesh foods (i.e., meat, poultry, and fish) were irradiated under such conditions, there would be no deleterious effect on the total dietary intake of thiamine as a result of irradiating flesh foods, including meat (62 FR 64107 at 64115).

In summary, based on the available data and information, FDA concludes that amending the regulations, as set forth in this document, to allow for the use of ionizing radiation to treat unrefrigerated meat up to a maximum dose of 4.5 kGy will not have an adverse impact on the nutritional adequacy of the overall diet.

D. Microbiological Considerations

FDA previously examined the effects of radiation-induced changes in the microbiological profile of meat and on the growth patterns of any surviving microorganisms, including Clostridium botulinum, to determine whether the microbiological safety of meat will be adversely affected by irradiation (62 FR 64107 at 64115). The Agency determined that irradiation of frozen and refrigerated meat and meat byproducts at a dose up to 4.5 kGy will not result in any additional health hazard from C. botulinum. Likewise, FDA also determined that irradiation will not result in any additional hazard from common pathogens other than C. botulinum (Ref. 18).

The Agency has determined that, although the use would be modestly different in the current petitioned request, the microbial hazards that carcasses would be subjected to would be equivalent to the microbial hazards from meat that has been further processed, i.e., meat from a completely broken-down carcass that has been refrigerated. Moreover, the same doses of irradiation would be expected to be equally effective in lowering levels of pathogenic and spoilage microorganisms.⁵ Therefore, the Agency concludes, based on all the evidence before it, that irradiation of meat under the conditions set forth in the regulation presented in this document will not result in a microbiological hazard (Ref. 18).

In summary, based on the available data and information, FDA concludes that irradiation of meat conducted in accordance with good manufacturing practices will reduce or eliminate bacterial populations with no increased microbial risk from pathogens that may survive the irradiation process (Ref. 18).

III. Labeling

The meat products covered by this rule are defined under the Federal Meat Inspection Act (21 U.S.C. 601, et seq.). Therefore, the labeling of these products irradiated under the conditions set forth in the regulation must comply with any requirements imposed by USDA/FSIS under its authority to approve the labeling of such products.

IV. Comments

FDA has received numerous comments, primarily form letters, from individuals that state their opinions regarding the potential dangers and unacceptability of irradiating food. FDA has also received several comments from individuals or organizations that state their opinions

⁵ USDA/FSIS provided a list of pertinent pathogens from sources of the meat they regulate and irradiation D-values (conditions under which 90 percent of the microorganisms have been eliminated) derived from published sources. D-values are typically obtained at various temperatures and FDA considers the food matrix to be more important than temperature for D-values.

regarding the potential benefits of irradiating food and urging FDA to approve the petition.

Additionally, FDA received several comments from Public Citizen (PC) and the Center for Food Safety (CFS) requesting the denial of this and other food irradiation petitions.

Overall, the comments were of a general nature and not necessarily specific to the requests in the individual petitions, and did not contain any substantive information that could be used in a safety evaluation of irradiated meat. Many of these comments from PC and CFS were also submitted to the docket for this Agency rulemaking on irradiation of molluscan shellfish (Docket No. 1999F-4372, FAP 9M4682). The topics raised in these comments included the following: Studies reviewed in the 1999 Food and Agriculture Organization of the United Nations/International Atomic Energy Agency/World Health Organization (FAO/IAEA/WHO) report on high-dose irradiation; a review article that analyzed studies of irradiated foods performed in the 1950s and 1960s; the findings of a 1971 study in which rats were fed irradiated strawberries; the findings regarding reproductive performance in a 1954 study in which mice were fed a special irradiated diet; issues regarding mutagenicity studies; certain international opinions; issues related to 2-ACBs, including purported promotion of colon cancer; the findings of certain studies conducted by the Indian Institute of Nutrition in the 1970s; general issues regarding toxicity data; FDA's purported failure to meet certain statutory requirements; data from a 2002 study purportedly showing an irradiation-induced increase in trans fatty acids in ground beef; studies regarding purported elevated hemoglobin levels and their significance; and an affidavit describing the opinions of a scientist regarding the dangers of irradiation and advocating the use of alternative methods for reducing the risk of foodborne disease. These comments have all been addressed by FDA in a previous rulemaking. For a detailed discussion of the Agency's response to each of the previous general comments, the reader is referred to the

molluscan shellfish rule (70 FR 48057 at 48062 through 48071). Because these comments do not raise issues specific to irradiated meat and meat byproducts, and the previous responses are sufficient to address these issues as they pertain to the rule to permit the irradiation of meat as described in this document, the Agency will not address these comments further here.

V. Conclusions

Based on the data and studies submitted in the petition and other information in the Agency's files, FDA concludes that the proposed use of irradiation to provide for the safe use of a 4.5 kGy maximum dose of ionizing radiation to treat unrefrigerated (as well as refrigerated) uncooked meat, meat byproducts, and certain meat food products to reduce levels of foodborne pathogens and extend shelf-life is safe, and therefore the regulations in § 179.26 should be amended as set forth in this document.

In accordance with §171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the use of irradiation of unrefrigerated meat in response to the petition will be made available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person (see FOR FURTHER INFORMATION CONTACT). As provided in §171.1(h), the Agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

VI. Paperwork Reduction Act of 1995

This final rule does not provide for the collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VII. Environmental Impact

The Agency has carefully considered the potential environmental effects of this action. The Agency has determined under 21 CFR 25.32(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Objections

Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (see ADDRESSES) either electronic or written objections. Each objection must be separately numbered, and each numbered objection must specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested must specifically so state. Failure to request a hearing for any particular objection constitutes a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested must include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection constitutes a waiver of the right to a hearing on the objection. It is only necessary to send one set of documents. Identify documents with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IX. Section 301(l) of the Federal Food, Drug, and Cosmetic Act

FDA's review of this petition was limited to section 409 of the FD&C Act. This final rule is not a statement regarding compliance with other sections of the FD&C Act. For example, the

Food and Drug Administration Amendments Act of 2007, which was signed into law on September 27, 2007, amended the FD&C Act to, among other things, add section 301(ll) (21 U.S.C. 331(ll)). Section 301(ll) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act (21 U.S.C. 355), a biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), or a drug or biological product for which substantial clinical investigations have been instituted and their existence has been made public, unless one of the exceptions in section 301(ll)(1) to (ll)(4) of the FD&C Act applies. In our review of this petition, FDA did not consider whether section 301(ll) of the FD&C Act or any of its exemptions apply to the ionizing radiation source. Accordingly, this final rule should not be construed to be a statement that ionizing radiation used to treat meat, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll) of the FD&C Act. Furthermore, this language is included in all food additive final rules and therefore, should not be construed to be a statement of the likelihood that section 301(ll) of the FD&C Act applies.

X. References

The following sources are referred to in this document. References marked with an asterisk (*) have been placed on display at the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>. References without asterisks are not on display; they are available as published articles and books.

1. Memorandum for FAP 9M4695 from K. Morehouse, FDA, to L. Highbarger, FDA, dated August 10, 2010.*

2. Diehl, J. F., “Chemical Effects of Ionizing Radiation,” pp. 43-88, in Safety of

Irradiated Foods, Second Edition, Marcel Dekker, Inc., New York, 1995.

3. Elias, P. S. and A. J. Cohen, "Recent Advances in Food Irradiation," Elsevier Biomedical, Amsterdam, 1983.

4. World Health Organization, "High-Dose Irradiation: Wholesomeness of Food Irradiated With Doses Above 10 kGy," World Health Organization Technical Report Series No. 890, pp. 9-37, Geneva, 1999.

5. Preservation of Food by Ionizing Radiation, edited by E. S. Josephson, and M. S. Peterson, Vol. II, CRC Press, Boca Raton, 1982.

6. Diehl, J. F., "Radiolytic Effects in Foods," pp. 279-357, in Preservation of Food By Ionizing Radiation, Vol. I, edited by E. S. Josephson, and M. S. Peterson, CRC Press, Boca Raton, 1982.

7. Crone, A. V. J., et al., "Effect of Storage and Cooking on the Dose Response of 2-Dodecylcyclobutanone, a Potential Marker for Irradiated Chicken," Journal of the Science of Food and Agriculture, 58:249-252, 1992.

8. Gadgil, P., K. A. Hachmeister, J. S. Smith, and D. H. Kropf, "2-Alkylcyclobutanones as Irradiation Dose Indicators in Irradiated Ground Beef Patties," Journal of Agriculture and Food Chemistry, 50:5746-5750, 2002.

9. Seibersdorf Project Report, International Programme on Irradiation of Fruit and Fruit Juices, Chemistry and Isotopes Department, National Centre for Nuclear Energy, Madrid, Spain, Vol. 8, 1966.

10. Memorandum for FAP 9M4695 from K. Morehouse, FDA, to L. Highbarger, FDA, dated May 18, 2009.*

11. Locas, C.; and V. A. Yaylayan, "Origin and Mechanistic Pathways of

Formation of the Parent Furan--a Toxicant,” Journal of Agricultural and Food Chemistry, 52:6830-6836, 2005.

12. Fan, X., and K. J. B. Sokorai, “Effect of Ionizing Radiation on Furan Formation in Fresh-Cut Fruits and Vegetables,” Journal of Food Science, 73(2): C79-C83, 2008.

13. Memorandum from Food Additives Evaluation Branch, FDA (HFS-156), to C. Takaguchi, Petition Control Branch, FDA, December 28, 1982.*

14. Memorandum for FAP 9M4696 from E. Jensen, FDA, to R. Alrefai, FDA, dated December 10, 1999.*

15. Memorandum to the file for FAP 4M4428, from D. Hattan, FDA, dated November 18, 1997.*

16. Underdal, B., J. Nordal, G. Lunde, and B. Eggum, “The Effect of Ionizing Radiation on the Nutritional Value of Fish (Cod) Protein,” Lebensmittel Wissenschaft Technologie, 6:90-93, 1973.

17. Diehl, J. F., “Nutritional Adequacy of Irradiated Foods,” pp. 241-282, in Safety of Irradiated Foods, Marcel Dekker, New York, 1995.

18. Memorandum for FAP 9M4695 from R. Merker, FDA, to L. Highbarger, FDA, dated May 26, 2010.*

19. Merritt, C., Jr., P. Angelini, E. Wierbicki, and G. W. Shults, “Chemical Changes Associated With Flavor in Irradiated Meat,” Journal of Agricultural and Food Chemistry, 23:1037-1041, 1975.

List of Subjects in 21 CFR Part 179

Food additives, Food labeling, Food packaging, Radiation protection, Reporting and recordkeeping requirements, Signs and symbols.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 179 is amended as follows:

PART 179--IRRADIATION IN THE PRODUCTION, PROCESSING AND HANDLING OF FOOD

1. The authority citation for 21 CFR part 179 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 348, 373, 374.

2. Section 179.26 is amended in the table in paragraph (b) by adding a new entry “13.” under the headings “Use” and “Limitations” to read as follows:

§ 179.26 Ionizing radiation for the treatment of food.

* * * * *

(b) * * *

Use	Limitations
* * *	* * *
13. For control of foodborne pathogens, and extension of shelf-life, in unrefrigerated (as well as refrigerated) uncooked meat, meat byproducts, and certain meat food products.	Not to exceed 4.5 kGy.

* * * * *

Dated: November 27, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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